## REMARKS

Reconsideration of this application is respectfully requested. Claim 28 has been amended to recite the step of orally administering a pharmaceutical composition comprising a biologically active agent and an effective amount of a compound of claim 1 to facilitate oral delivery of the biologically active agent. Claim 28 has also been amended to specify that the biologically active agent is selected from the same list of agents as recited in allowed claim 5. Support for these amendments can be found at, for example, original claim 5 and page 3, lines 21-25, page 7, lines 12-17 and 30-33, page 8, lines 1-33, and page 9, lines 1-17, of the specification. No new matter has been added by this amendment. Claims 1-12 and 15-31 are pending. Because claims 1-12, 15-27 and 29-31 have been allowed, only claim 28 is at issue.

### I. Indefiniteness Rejection

Claim 28 stands rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. The Examiner contends that the claim fails to state the function which is to be rendered effective and the amount. Applicants respectfully traverse this rejection and request reconsideration.

Without conceding the correctness of the Examiner's position, claim 28 has been amended to recite an effective amount of the compound of claim 1 to facilitate oral delivery of the biologically-active agent. Applicants are unclear as to what the Examiner means by the statement that "the claim fails to state the function, which is to be rendered effective." The function of the claimed method is to administer a biologically-active agent orally. As discussed in the background section of the application, many biologically-active agents are not typically amenable to oral delivery because of biological, chemical, and physical barriers (page 2, lines 7-21, of the specification). The compound of claim 1, when administered with the biologically-active agent, facilitates the delivery of the agent through these barriers without degradation.

Applicants respectfully submit that an amount of the biologically-active agent need not be recited as the purpose of the claimed method is not to treat a particular disease but to administer the agent to an animal.

For the foregoing reasons, applicants respectfully submit that claim 28 is definite and request withdrawal of this rejection.

**II. Enablement Rejection**

Claim 28 stands rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner contends that the specification while enabling for heparin, rhGH, PTH-34, interferon and insulin delivery systems does not provide enablement for all delivery systems containing active agents other than those listed. Applicants respectfully traverse this rejection and request reconsideration.

Without conceding the correctness of the Examiner's position, claim 28 has been amended to recite the biologically active agents listed in allowed claim 5.

Applicant submits that the Examiner has the initial burden of establishing a reasonable basis to question the enablement of the claims. According to the M.P.E.P.:

> In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. ... As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth

> or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.

M.P.E.P. § 2164.04.

The Examiner has not provided any reason to doubt the objective truth that the compound of claim 1 can be formulated with active agents into pharmaceutical compositions. The examples in the application show (and the Examiner acknowledges) that the compound of claim 1 effectively delivers heparin, recombinant human growth hormone (rhGH), parathyroid hormone 1-34 (pTH 1-34), interferon, and insulin. These active agents are of different classes (e.g., heparin is a mucopolysaccharide and recombinant human growth hormone is a peptide), different sizes, and serve significantly varying functions. This data establishes that the compound recited in claim 1 can effectively deliver a wide array of active agents.

Additionally, even assuming, *arguendo*, that some pharmaceutical compositions containing the compound of the present invention and a biologically-active agent are inoperable, the claims would still be properly enabled. As stated in the M.P.E.P.:

> The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984) (prophetic examples do not make the disclosure nonenabling).

M.P.E.P. § 2164.08(b).

Because designing and preparing pharmaceutical formulations is a well known and understood art, one of ordinary skill in the art could determine which embodiments, if any, would be inoperative with the expenditure of no more effort than is normally required in the art.

For the foregoing reasons, undue experimentation would not be required to perform the method recited in claim 28. Accordingly, claim 28 does not lack enablement, and applicants respectfully request withdrawal of this rejection.

In view of the above amendments and arguments, the pending claims in this application are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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